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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,658	12/31/2000	Rolfe C. Anderson	1087.3A-1.1(37US4)	8815

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EXAMINER

BEISNER, WILLIAM H

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 02/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/751,658

Applicant(s)

ANDERSON ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 90-135 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 90-135 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 21
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02 Dec. 2002 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 90-135 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 90, the step of "providing a diaphragm valve" is indefinite. The claim recites providing first and second chambers in fluid communication wherein each chamber includes a vent port and one chamber is a volumetric chamber having a known volume. It is not clear how the recited diaphragm valve structurally cooperates with the previously recited structure of the provided device. What does the valve cooperate with, the vent ports, the channel, the chamber, etc.? Additionally, the recited filling and transporting steps are indefinite because it is not clear how the recited filling and transporting are performed in view of the recited structures of the provided device. That is, while the instant language recites filling the volumetric chamber and

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transporting the fluid from the volumetric chamber to the second chamber, the claim is devoid of any positively recited language which incorporates the recited valve, channel, or ports with respect to the filling and transporting steps. Furthermore, with respect to the recited vent ports, how can the chambers be filled without the loss of fluid from the ports? Also, how can a **known volume of fluid** be transferred from one chamber to another if the connecting channel also contains a fluid?

In claim 92, the step of “providing a sealable closure inlet” and “providing at least one valve” are indefinite. The claim recites providing first and second chambers wherein each chamber includes a vent port and one chamber is a volumetric chamber having a known volume. It is not clear how the recited sealable inlet and valve structurally cooperates with the previously recited structure of the provided device. What do the inlet and the valve cooperate with, the vent ports, the chamber, etc.? The claims do not even recite that the chambers are in any type of communication. Additionally, the recited filling and transporting steps are indefinite because it is not clear how the recited filling and transporting are performed in view of the recited structures of the provided device. That is, while the instant language recites filling the volumetric chamber and transporting the fluid from the volumetric chamber to the second chamber, the claim is devoid of any positively recited language that incorporates the recited inlet, valve or ports with respect to the filling and transporting steps. What function does opening the valve serve? How does this opening cause fluid to be transported? The claim does not even recite with respect to what positively recited structure the valve cooperates with. Furthermore, with respect to the recited vent ports, how can the chambers be filled without the loss of fluid

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from the ports? Also, how can a known volume of fluid be transferred from one chamber to another if the connecting channel also contains a fluid?

In claims 93, 96, 97 and 132, in view of the structures recited in claim 92, how is a positive pressure applied to the volumetric chamber? How does the pneumatic system of claims 96 and 97 cooperate with the elements of claim 93, if at all?

In claim 94, in view of the structures recited in claim 92, how is the volumetric chamber vented?

Claims 98-100 and 133 are indefinite for the same reasons as set forth with respect to claims 93, 96 and 97.

With respect to claims 101-116, while the claims recite further method steps, the claims are devoid of any positively recited language which recites how these further method steps are performed in view of the structural elements required of the language of claim 92 from which these claims depend.

In claim 117, the recited "a sealable closure inlet" and "at least one valve" are indefinite. The claim recites a device that includes first and second chambers wherein each chamber includes a vent port and one chamber is a volumetric chamber having a known volume. It is not clear how the recited sealable inlet and valve structurally cooperates with the previously recited structure of the provided device. The claim does not even recite that the chambers are provided in fluid communication. What do the inlet and the valve cooperate with, the vent ports, the chambers, etc.? Additionally, the recited "means for filling" and "means for transporting" are indefinite. These recited means would appear to require the use of the previously recited structural elements in the claim to perform the required functions, i.e., require the use of the

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valve, vent ports, etc., however, the instant claim language fails to recite how the means cooperate with these elements. Also, it would appear that the recited valve would actually be part of the recited means for filling and/or transporting. Clarification and/or correction is requested. Furthermore, with respect to the recited vent ports, how can the chambers be filled without the loss of fluid from the ports? Also, how can a **known volume of fluid** be transferred from one chamber to another if the connecting channel also contains a fluid?

Claims 118-126 are indefinite because while the claims recite further means associated with the device, the claim language is devoid of positively recited claim language which recites how the further recited means structurally cooperate with the positively recited structure of the device of claim 117.

Claims 127-131 are indefinite because it is not clear how the fluid and method limitations of these claims further limit the structure of the device of claim 117.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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5. Claims 90, 91, 132 and 133 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-8 of U.S. Patent No. 6,197,595 in view of Webster (US 4,858,883). Claims 6-8 of U.S. Patent 6,197,595 encompass a method of measuring and directing a known volume of a fluid sample within a microfluidic device. While the method employs controllable valves, the instant claims require the use of a diaphragm valve. The reference of Webster (US 4,858,883) discloses that the use of diaphragm valves are known in microfluidic devices (See Figure 1). In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a diaphragm valve in the method of the patented claims for the known and expected result of providing a means recognized in the art for achieve the desired result of controlling the flow of fluid within a microfluidic device.

6. Claims 92-116 and 134 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-8 of U.S. Patent No. 6,197,595 in view of Wilding et al.(US 5,498,392). Claims 6-8 of U.S. Patent 6,197,595 encompass a method of measuring and directing a known volume of a fluid sample within a microfluidic device. While the method employs controllable valves, the instant claims require the use of a sealable port and the use of nucleic acid reaction and detection techniques. The reference of Wilding et al. discloses a microfluidic device which includes a sample introduction port (51) and a plurality of nucleic acid reaction and detection structures (See the entire disclosure). In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the method

encompassed by the patented claims to perform nucleic acid reactions and/or detections for the known and expected result of providing a known volume of sample material to the device.

7. Claims 117-131 and 135 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-58 of U.S. Patent No. 5,922,591 in view of Wilding et al. (US 5,498,392). Claims 1-58 of U.S. Patent No. 5,922,591 encompass a device which is structurally similar to the device of the instant claims. The device of the patent claims includes at least two chambers connected by a common channel wherein each chamber includes a vent port and the device includes a controllable valve and an external pressure source for controlling the valve and the flow of fluid between the chambers and channel. The instant claims differ by reciting that the device includes a sealable inlet port. The reference of Wilding et al. discloses that it is known in the art to provide a microfluidic device with sealable ports for the introduction of sample and reagents into the fluidic system (See column 14, lines 11-37). In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of the patented claims with a sealable port for the known and expected result of providing a means recognized in the art for introducing sample and/or reagents into the sealed microfluidic reaction system.

Response to Arguments

8. Applicant's arguments with respect to the newly amended claims have been considered but are moot in view of the new ground(s) of rejection.

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9. Applicant's arguments filed 02 Dec. 2002 have been fully considered but they are not persuasive.

With respect to the obviousness-type double patenting rejection of record, applicants argue that the rejection is improper because the claims of the instant application were subject to a restriction requirement in the parent application (08/671,928) of the application which issued as U.S. Patent No. 6,197,595.

Applicants' comments are not found to be persuasive for the following reason;

In this restriction requirement set forth in parent application 08/671,928), Group II consisted of claims 84-88 and Group IV consisted of claims 90-91. Claims 84-88 of Group II correspond to claims 1-5 of U.S. Patent No. 6,197,595. Claims 6-8 of U.S. Patent No. 6,197,595 were added during prosecution of application 09/294,700 and were not part of the claims of the original restriction requirement.


Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



William H. Beisner
Primary Examiner
Art Unit 1744

WHB
February 10, 2003